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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,399	05/10/2005	Kazuyuki Miyazawa	TOS-162-USA-PCT	2841
27955 TOWNSEND &	7590 05/29/2007 & RANTA		EXAMINER	
c/o PORTFOLIO IP PO BOX 52050 MINNEAPOLIS, MN 55402			LOEWE, ROBERT S	
			ART UNIT	PAPER NUMBER
	20, 2011 00 102		1709	
			MAIL DATE	DELIVERY MODE
			05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

· · · · · · · · · · · · · · · · · · ·	Application No.	Applicant(s)				
	10/534,399	MIYAZAWA ET AL.				
Office Action Summary	Examiner	Art Unit				
	Robert Loewe	1709				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUN 36(a). In no event, however, may a fill apply and will expire SIX (6) MC cause the application to become A	IICATION.  The reply be timely filed  ONTHS from the mailing date of this communication.  ABANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 10 Ma	1) Responsive to communication(s) filed on 10 May 2005.					
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-3 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-3</u> is/are rejected.		•				
7) Claim(s) 2-3 is/are objected to.	oloction requirement					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner	r: <sub>0</sub>					
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Exa	aminer. Note the attache	ed Oπice Action or form P1O-152.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
	or the defined copies no	rieceived.				
Attachment(s)	_					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  2) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 01/07.  5) Notice of Informal Patent Application 6) Other:						

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#### **DETAILED ACTION**

### Claim Objections

Claim 2 is objected to because of the following informalities: Formula (7) needs to be corrected. Specifically, the claim states that  $R_5$  may be hydrogen or an alkyl group having 1-22 carbon atoms. Formula (7) shows  $R_5$  as OH. Formula (7) needs to be changed from OH to  $OR_5$ , both in the claims and in the specification. Appropriate correction is required.

Claim 2 is objected to because of the lack of antecedent basis of the term "said formula (1). Since claim 2 is an independent claim, it cannot rely on claim terms introduced in other claims.

Claim 3 is objected to because of the following informalities: the periods placed in claim 3 need to be removed except the last one.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph as being indefinite since it lacks any respective relationship between formulas (2), (3), and (4) with formulas (5), (6), and (7). For purposes of the examination, the examiner assumes that a respective relationship does exist for these two formula groups.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al (Macromolecules 1995, 28, 2590-91). Yamada et al. teach a polysiloxane containing a phosphorylcholine group represented by the general formula (1) of the instant application (see Scheme 1).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al., (Macromolecules 1995, 28, 2590-2591) in view of either Lewis et al. (US Pat. 6,828,029) or Koontz (US Pat. 5,369,012).

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Yamada et al. teaches (Scheme 1) the basic polymer in formula (5) of instant claim 2.

The Yamada et al. reference does not teach n equal to 1-22 or the presence of an amino spacer.

Lewis et al. (example 7) and Koontz et al. (example 4) teach polysiloxanes containing phosphorylcholine groups. The teachings of Yamada et al. and either Lewis et al. or Koontz et al. are combinable because they are from the same field of endeavor, namely, the preparation of biocompatible materials, specifically, phosphorylcholine-modified polysiloxanes. At the time of invention, a person or ordinary skill in the art would have found it obvious to have explored alternate chemistries for the attachment of phosphorylcholine moieties to polysiloxane backbones and would have been motivated to do so since the biocompatibility of the polymers prepared by Lewis and Koontz is preserved even with the structural differences shown by these teachings. See MPEP 2144.09. The artisan should also expect a reasonable expectation of success independent of the method for the introduction of the phosphorylcholine moiety to the polysiloxane backbone based on the teachings described above.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liberda et al. (Chimia 1999, 53, 528-532) in view of Pery et al. (US Pat. 4,203,893).

Liberda et al. teaches reaction of the same phosphorylcholine aldehyde disclosed in the instant specification with a polymeric substrate (poly(acrylamide-allylamine) copolymer) following the same method as instant claim 3 (Scheme on p. 529). Liberda et al. does not teach this reaction for polysiloxanes.

Pery et al. teaches the method of instant claim 3 using a cytidine-phosphorylcholine aldehyde starting material (Example 1). Liberda et al. and Pery et al. are combinable because

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they are from the same field of endeavor, namely, a method to prepare phosphorylcholine modified materials. At the time of invention, a person having ordinary skill in the art would have found it obvious to employ an amine-modified polysiloxane starting material and would have been motivated to do so since Liberda et al. teaches that polymers are useful starting materials for the aldehyde plus amine condensation reaction of instant claim 3 and Pery et al. teach that compounds which contain a free amino group are suitable for use in the aldehyde plus amine condensation reaction (2:37-39).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stults et al. teach another embodiment of the reaction method of instant claim 1. Rii et al. (translation provided) teach that the phosphorylcholine aldehyde disclosed in the instant specification can be reacted with a polymer having an amino group. See attached form PTO-892.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Loewe whose telephone number is (571) 272-1197. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000-7

RSL

22-May-2007

MARK EASHOO, PH.D PRIMARY EXAMINER

23/May 107